

# Clinical Trials

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## Management of clinical trial agreements

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Clinical trial agreements are legal and binding, forming the foundation for a successful partnership between study sites and sponsors. Not understanding the legal language and the terms of the contract can lead to financial and legal ramifications for the site, the investigator, and study staff. Terms and language of the contract will be reviewed focusing on risk areas and protecting the site. Through interactive activities participants will review and revise contract language to meet the needs of the site. Proper management of contracts includes knowing what you are agreeing to, prioritizing site needs, and utilizing site metrics and successful strategies to negotiate a fair and balanced contract. Strategies include redlining contracts with preferred language, naming and version control, reviewing related study documents for consistency, contract definitions, addressing the responsibilities of the contract parties, and asking questions for clarification. The session will finish with contract tips.

## Biography

JoAnn Pfeiffer has completed her Doctorate of Science, in Regulatory Science from the University of Southern California. She is currently the Director and an Associate Professor, in the Clinical Research Management Graduate Program at Arizona State University. She has published several books related to managing contracts and budgets in clinical trials, conducting clinical trials at study sites, as well as articles in peer reviewed journals. Her experience includes over 20 years in the management of clinical trial operations in both academic and non-academic settings.

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